SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6381–6400

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (National Formulary), and its quality and purity fell below the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name and quantity or proportion of such derivative, and in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2) in the case where it was fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of alcohol; Section 502(f)(1), the labeling of the article failed to bear adequate directions for use and the article was not exempt from such requirement; Section 503(b)(1), the article was a drug intended for use by man which, because of its toxicity or other potentiality for harmful effect, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug and it was dispensed contrary to the provisions of such Section; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6381. Acutalyn. (F.D.C. No. 42492. S. Nos. 69–077 M, 83–679 M.)

INFORMATION FILED: 10–14–60, N. Dist. Calif., against Enzyme Products, Inc., San Leandro, Calif., and Wesley G. Irons, vice-president.

SHIPPED: On 6–12–57 and 6–21–57, from San Leandro, Calif., to Jackson Heights, N.Y., and Peoria, Ill.

LABEL IN PART: (Vial) "5 cc Single Dose Vial ACUTALYN For Intravenous Inject. Only ENZYME PRODUCTS, INC. San Leandro, Calif."

CHARGE: 505(a)—when shipped, the article was a new drug within the meaning of the law and an application filed pursuant to 505(b) was not effective with respect to such drug.

PLEA: Nolo contendere.

DISPOSITION: 12–12–60. Corporation—$500 fine; individual—$100 fine suspended.